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Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

mailed on
AUG 16 2012
OPLA

Attention: Beverly Friedman

The attached application for patent term extension of U.S. Patent No. 5,886,035 was filed on April 3, 2012, under 35 U.S.C. § 156.

The assistance of your Office is requested in confirming that the product identified in the application, ZIOPTAN® (tafluprost), has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use and that the application for patent term extension was filed within the sixty-day period beginning on the date the product was approved. Since a determination has not been made whether the patent in question claims a product which has been subject to the Federal Food, Drug and Cosmetic Act, or a method of manufacturing or use of such a product, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156.

Inquiries regarding this communication should be directed to the undersigned at (571) 272-7755 (telephone) or (571) 273-7755 (facsimile).

Mary C. Till
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Associate Commissioner
for Patent Examination Policy

cc: Sylvia A. Ayler
Merck & Co., Inc.
IP Group
P.O. Box 2000
Rahway, NJ 07065-0907

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Sylvia A. Ayler
Merck & Co., Inc.
IP Group
P.O. Box 2000
Rahway, NJ 07065-0907

In Re: Patent Term Extension
Application for
U.S. Patent No. 5,886,035

Filing Date: April 3, 2012

mailed on
AUG 16 2012
OPLA

REQUIREMENT FOR INFORMATION PURSUANT TO 37 C.F.R. 1.750

An application for extension of the patent term (PTE Application) of U.S. Patent No. 5,886,035 (the '035 patent) under 35 U.S.C. § 156 was filed in the United States Patent and Trademark Office on April 3, 2012. The application was filed by Merck & Co., agent for patent owners Asahi Glass Company Ltd and Santen Pharmaceutical Com., Ltd. Extension is sought based upon the premarket review under § 505 of the Federal Food Drug and Cosmetic Act of the human drug product ZIOPTAN® (tafluprost). A New Drug Application (NDA) for ZIOPTAN® (NDA No. 202514)was granted approval by the Food and Drug Administration (FDA) on April 10, 2012.

The following errors or omissions are noted in the PTE Application:

(1) Page 1 indicates the issue date sis December 18, 2017.

(2) Attachment A1 is undated and the header indicates the incorrect patent number.

(3) An Original and one copy was submitted. As per 37 C.F.R. 1.740(b) an original and 2 copies are required. An additional copy is needed.

Applicant is given a TIME PERIOD of ONE (1) MONTH or THIRTY (30) DAYS from the mailing date of this notice, whichever is longer, to comply with the requirements enumerated above. Extensions of time under 37 C.F.R. 1.136(a) are not applicable to this time period. If no corrective action is taken, the documents relating to the PTE Application will be placed in the official patent image file wrapper for the '035 patent without further action being taken.

Any correspondence from applicant with respect to this matter should be addressed as follows:

By mail: Commissioner for Patents
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

By FAX: (571) 273-7755
Attn: Office of Patent Legal Administration

Telephone inquiries related to this notice should be directed to the undersigned at (571) 272-7755.

Mary C. Till
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

Attention: Beverly Friedman

RE: ZIOPTAN® (tafluprost)
Docket No.: FDA-2012-